DETAILED ACTION

Response to Amendment

Examiner acknowledges the appeal brief filed 6/26/2007 in which the claims were rejection in view of Vito (USPN5,931,838) or Dahners et al. (USPN6,955,677) in view of de Groot (EP 0367354). Examiner withdraws the finality and the rejection in the final office action filed 1/3/2007 in view of new prior art (see below). Currently claims 1, 3-16 and 18-21 are pending for examination with claims 101-2 are withdrawn from a previous election restriction.

Specification

The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)…". (Also see **MPEP 2181** (Rev. 1, Feb.2000))

Appropriate correction is required.

Claim Objections

Claim 9 is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-9, 13-16, and 18-21 are rejected under 35 U.S.C 103(a) as being unpatentable over Poirier (USPN4,668,222) in view of de Groot (EP0367354).

Regarding claims 1, 3-9, 13-16 and 18-21, Poirier discloses medical device comprising: a stud (near 58) formed of a biocompatible material and configured to project percutaneously outward (see Figures 4-5) through a patient's skin layers (74, 52,

50); said stud (near 58) defining an outer end (near 20) and having a longitudinal peripheral surface extending inwardly from said outer end; said peripheral surface having a longitudinal porous layer (33) thereon for promoting soft tissue ingrowth; a shoulder surface (22) oriented substantially perpendicular to said stud peripheral surface and located inwardly from said stud outer end and from said longitudinal porous layer (33); and wherein said shoulder surface has a lateral porous layer thereon (near 34) oriented substantially perpendicular to said longitudinal porous layer for promoting soft tissue ingrowth and wherein at least one of said porous layers is characterized by a pore size within the range of 50 to 200 microns (col 3, ln 15-20, 40-65) and composed of a fibrous porous polymeric layer (PTFE, col 3, 15-17); and a cap (96) configured for mounting on the stud outer end (Figures 1-5, cols 1-2).

Poirier meets the claim limitations as described above except for the specific porosity and metallic materials.

However, de Groot teaches a percutaneous implant.

Regarding claims 1, 3-9, 13-16 and 18-21, de Groot teaches with a percutaneous implant (10) with a porous surface (3) which contains a sintered fibrous metal such as stainless steel a porosity of between 60% to 95% (Figures 1-2, col 2, ln 10-45).

At the time of the invention, it would have been obvious to use the porous materials of de Groot with the system of Poirier in order to allow for an alternate tissue ingrowth system for retaining the skin implant port. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one

skilled in the art would have combined the teachings in the references in light of the disclosure of de Groot (cols 1-2).

Claim Rejections - 35 USC § 103

Claims 1, 3-5, 7, 9, 13-16, and 18-20 are rejected under 35 U.S.C 103(a) as being unpatentable over Thramann (USPN5,360,448) in view of de Groot (EP0367354).

Regarding claims 1, 3-5, 7, 9, 13-16, and 18-20, Thramann discloses medical device comprising: a stud (near 11) formed of a biocompatible material (titanium) and capable of projecting percutaneously outward through a patient's skin layers; said stud (near 1) defining an outer end (near end of 11) and having a longitudinal peripheral surface extending inwardly from said outer end; said peripheral surface having a longitudinal porous layer (11) thereon for promoting soft tissue ingrowth; a shoulder surface (near 1) oriented substantially perpendicular to said stud peripheral surface and located inwardly from said stud outer end and from said longitudinal porous layer (11); and wherein said shoulder surface has a lateral porous layer thereon (near 10) oriented substantially perpendicular to said longitudinal porous layer capable of promoting soft tissue ingrowth and wherein at least one of said porous layers is characterized by a metallic sintered fibrous material (col 8, ln 25-60) and a cap (13, 21) configured for mounting on the stud outer end (Figures 1-6B, cols 1-2).

Poirier meets the claim limitations as described above except for the specific pore size and porosity.

However, de Groot teaches a percutaneous implant.

Regarding claims 1, 3-5, 7, 9, 13-16, and 18-20, de Groot teaches with a percutaneous implant (10) with a porous surface (3) which contains a sintered fibrous metal such with a pore size within the range of 50 to 200 microns and a porosity of between 60% to 95% (Figures 1-2, col 2, ln 10-45).

At the time of the invention, it would have been obvious to use the porous materials of de Groot with the system of Thramann in order to allow for an alternate tissue ingrowth system for retaining the skin implant port. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of de Groot (cols 1-2).

Response to Arguments

Applicant's arguments with respect to claims 1, 3-9, 13-16 and 18-21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER D. KOHARSKI whose telephone number is (571)272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 3/20/2008

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763